Remarks

The Office action mailed July 14, 2004, has been received and reviewed. Claims 25-30, 55-60 and 85-90 were elected in a response to a restriction requirement. As such, claims 25-30, 55-60 and 85-90 are pending herein. Reconsideration of the application in view of the following remarks is respectfully requested.

Amendments to the Drawings

In amended Figure 5, the drawing as been amended so that the elements of the Figure are not obscured or difficult to see due to dark shading in the Figure.

35 U.S.C. § 103(a) Rejections

A.) Applicable Authority

The basic requirements of a *prima facie* case of obviousness are summarized in MPEP §2143 through §2143.03. In order "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP § 2143. Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in

light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985)." *Id. See also* MPEP §706.02(j) and §2142.

B.) Obviousness Rejection Based on the Ichikawa, Evans and Sundberg References

Claims 25-26, 29-30, 55-56, 59-60, 85-86 and 89-90 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference (Internal Medicine (July 200) Vol. 39, no. 7, pp. 523-524) in view of the Evans reference (Science (Oct. 1999) Vol. 286, pp 487-491) and the Sundberg reference (J. Clin. Pharm. (2000) vol. 40, pp. 930-938). As the Ichickawa, Evans and Sundberg references fail to teach or suggest all the limitations of the rejected claims, Applicant respectfully traverses this rejection, as hereinafter set forth.

Dependent claims 26 and 29-30 each depend directly or indirectly from independent claim 25. Independent claim 25 is directed to a method in a computer system for processing hereditary data related to the use of clinical agents by a person, comprising the steps of receiving a genetic test result value for the person, determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents and outputting an interpretation of the genetic test result value and the list of risk-associated agents. It is respectfully submitted that the Ichickawa, Evans and Sundberg references fail to teach or suggest a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event an outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 25.

More particularly, the Ichickawa reference fails to teach or suggest, the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a

polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 25. Rather, the method of the Ichickawa reference teaches that a particular single nucleotide polymorphism can be used to disclose severe side effects or proper dosage for a patient. The Ichickawa reference lacks any teaching or suggestion of computerized steps of accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system. The Ichickawa reference merely teaches a patient with an autosomal recessive trait for TMPT deficiency may show severe and potentially fatal leukopekia if treated with aqathioprine or mercaptopurine. There is no suggestion in the Ichickawa reference to automate accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting interpretation of one or more genetic test result values and a list of risk-associated agents in a computerized system without user intervention. (See Office Action 7/14/2004, Page 5)

The Evans reference also fails to teach or suggest a method in a computer system the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 25. Rather, the Evans reference discloses translating functional genomics into rational therapeutics. The Evans reference provides examples of clinically relevant genetic polymorphisms influencing drug metabolism and effects. The Evans reference lacks any teaching or suggestion of computerized steps for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents. The Evans reference merely chronicles the fact that automated systems are being

developed to determine an individual's genotype for polymorphic genes. The discussion of automated systems is limited to automated systems for determining an individual's genotype and does not discuss accessing and outputting a list of risk-associated agents for a particular genotype. There is no teaching or suggestion in Evans that an automated computer system may be used to associate an individual's genotype for a polymorphic gene with a list of risk-associated agents and outputting a list of risk-associated agents.

The Sundberg reference also fails to teach or suggest a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 25. Rather, the method of the Sundberg reference teaches that several examples exist where subjects carrying certain alleles suffer from a lack of drug efficacy due to ultra-rapid metabolism or adverse effects from the drug treatment due to both drug development and clinical practice. The Sundberg reference also teaches that drug industries regularly genotype patients and that it is advisable to include genotypes in the patient's medical record. However, the Sundberg reference lacks any teaching or suggestion of computerized steps for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system.

Accordingly, it is respectfully submitted that the Ichickawa, Evans and Sundberg references fail to teach or suggest all of the limitations of independent claim 25 and, thus, a *prima facie* case of obviousness cannot be established for this claim based upon the combination of the Ichickawa, Evans and Sundberg references. *See*, *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d

1438 (Fed. Cir. 1991). As claims 26 and 29-30 depend from independent claim 25, it is respectfully submitted that a *prima facie* case of obviousness based upon the combination of the Ichickawa, Evans and Sundberg references cannot be established for these claims for at least the same reasons as independent claim 25. *See, In re Fine*, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988) (a dependent claim is obvious only if the independent claim from which it depends is obvious); *see also*, MPEP § 2143.03. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 26 and 29-30 is respectfully requested.

Dependent claims 56 and 59-60 each depend directly or indirectly from claim 55. Independent claim 55 is directed to a computer system for processing hereditary data related to the use of clinical agents by a person, comprising a receiving component for receiving a genetic test result value for the person, a first determining component for determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and an accessing component for accessing a list of risk-associated agents if the determining component determines that a genetic test result value is a polymorphism value associated with an atypical event and an outputting component for outputting an interpretation of the genetic test result value and the list of risk-associated agents. It is respectfully submitted that the Ichickawa, Evans and Sundberg references fail to teach or suggest a computer system for processing hereditary data related to the use of clinical agents by a person that includes an accessing component for accessing a list of risk-associated agents and an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 55.

More particularly, the Ichickawa reference fails to teach or suggest, a computer system for processing hereditary data related to the use of clinical agents by a person that

includes an accessing component for accessing a list of risk-associated agents if the determining component determines that a genetic test result value is a polymorphism value associated with an atypical event and an outputting component for outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Rather, the method of the Ichickawa reference teaches that a particular single nucleotide polymorphism can be used to disclose severe side effects or proper dosage for a patient. The Ichickawa reference lacks any teaching or suggestion of an accessing component for accessing a list of risk-associated agents for a genetic test result value or an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system. The Ichickawa reference merely teaches a patient with an autosomal recessive trait for TMPT deficiency may show severe and potentially fatal leukopekia if treated with aqathioprine or mercaptopurine. There is no suggestion in the Ichickawa reference to use automated computer components such as an accessing component for accessing a list of risk-associated agents for genetic test result value or outputting component for outputting interpretation of one or more genetic test result values and a list of risk-associated agents in a computerized system without user intervention. (See Office Action 7/14/2004, Page 5)

The Evans reference also fails to teach or suggest, a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes automated computer components such as an accessing component for accessing a list of risk-associated agents for a genetic test result value and an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Again, the Evans reference translates functional genomics into

rational therapeutics. The Evans reference provides examples of clinically relevant genetic polymorphisms influencing drug metabolism and effects. However, the Evans reference lacks any teaching or suggestion of an accessing component for accessing a list of risk-associated agents and an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system. The Evans reference merely chronicles the fact that automated systems are being developed to determine an individual's genotype for polymorphic genes. The discussion of automated systems in the Evans reference limited to automated systems for determining a genotype not an accessing component for accessing a list of risk-associated agents for a genetic test result value and an outputting component for outputting a list of risk-associated agents for a particular genotype. There is no teaching or suggestion in Evans that an automated computer system may be used to associate an individual's genotype for a polymorphic gene with a list of risk-associated agents.

The Sundberg reference also fails to teach or suggest, in a computer system for processing hereditary data related to the use of clinical agents by a person that includes an accessing component for accessing a list of risk-associated agents if a determining component determines that a genetic value is a polymorphism value associated with an atypical event and an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Rather, the method of the Sundberg reference teaches that several examples exist where subjects carrying certain alleles suffer from a lack of drug efficacy due to ultra-rapid metabolism or adverse effects from the drug treatment due to both drug development and clinical practice. The Sundberg reference also teaches that drug industries regularly genotype patients and that it is advisable to include genotypes in the patient's medical record. The Sundberg reference lacks any teaching or

suggestion of an accessing component for accessing a list of risk–associated agents if a determining component determines a genetic test result value is a polymorphism value associated with an atypical event and an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system.

Accordingly, it is respectfully submitted that the Ichickawa, Evans and Sundberg references fail to teach or suggest all of the limitations of independent claim 55 and, thus, a *prima facie* case of obviousness cannot be established for this claim based upon the combination of the Ichickawa, Evans and Sundberg references. *See*, *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). As claims 56 and 59-60 depend from independent claim 55, it is respectfully submitted that a *prima facie* case of obviousness based upon the combination of the Ichickawa, Evans and Sundberg references cannot be established for these claims for at least the same reasons as independent claim 55. *See*, *In re Fine*, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988) (a dependent claim is obvious only if the independent claim from which it depends is obvious); *see also*, MPEP § 2143.03. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 56 and 59-60 is respectfully requested.

Dependent claims 86 and 89-90 each depend directly or indirectly from claim 85. Independent claim 85 is directed to a computer readable medium comprising instructions for processing hereditary data related to the use of clinical agents by a person, comprising the steps of receiving a genetic test result value for the person, determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents and outputting an interpretation of the genetic test result value and the list of risk-associated agents. It is respectfully submitted that the Ichickawa, Evans and Sundberg references fail to teach or suggest a computer readable medium comprising instructions for

processing hereditary data related to the use of clinical agents by a person that includes accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 85.

More particularly, the Ichickawa reference fails to teach or suggest instructions on a computer readable medium that includes accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 85. Rather, the method of the Ichickawa reference teaches that a particular single nucleotide polymorphism can be used to disclose severe side effects or proper dosage for a patient. The Ichickawa reference lacks any teaching or suggestion instructions on a computer readable medium for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system. The Ichickawa reference merely teaches a patient with an autosomal recessive trait for TMPT deficiency may show severe and potentially fatal leukopekia if treated with aqathioprine or mercaptopurine. There is no suggestion in the Ichickawa reference to automate accessing a list of risk-associated agents and outputting interpretation of one or more genetic test result values and a list of risk-associated agents in a computerized system without user intervention. (See Office Action 7/14/2004, Page 5)

The Evans reference also fails to teach or suggest a computer-readable medium for processing hereditary data related to the use of clinical agents by a person that includes comprising instruction for accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent

claim 85. Rather, the Evans reference translating functional genomics into rational therapeutics. The Evans reference provides examples of clinically relevant genetic polymorphisms influencing drug metabolism and effects. However, the Evans reference lacks any teaching or suggestion of outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system. The Evans reference merely chronicles the fact that automated systems are being developed to determine an individual's genotype for polymorphic genes. The discussion of automated systems in Evans is limited to automated systems for determining a genotype and does not discuss computer instructions for accessing a list of risk-associated agents and outputting the list. There is no teaching or suggestion in Evans that an automated computer system may be used to associate an individual's genotype for a polymorphic gene with a list of risk-associated agents or output the list of risk-associated agents.

The Sundberg reference also fails to teach or suggest computer instructions for accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 85. Rather, the method of the Sundberg reference teaches that several examples exist where subjects carrying certain alleles suffer from a lack of drug efficacy due to ultra-rapid metabolism or adverse effects from the drug treatment due to both drug development and clinical practice. The Sundberg reference also teaches that drug industries regularly genotype patients and that it is advisable to include genotypes in the patient's medical record. However, the Sundberg reference lacks any teaching or suggestion of computer instructions for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system.

Accordingly, it is respectfully submitted that the Ichickawa, Evans and Sundberg references fails to teach or suggest all of the limitations of independent claim 85 and, thus, a *prima facie* case of obviousness cannot be established for this claim based upon these references. reference. *See*, *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). As claims 86 and 89-90 depend from independent claim 85, it is respectfully submitted that a *prima facie* case of obviousness based upon the Ichickawa, Evans and Sundberg references cannot be established for these claims for at least the same reasons as amended independent claim 85. *See*, *In re Fine*, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988) (a dependent claim is obvious only if the independent claim from which it depends is obvious); *see also*, MPEP § 2143.03. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 86 and 89-90 is respectfully requested.

C.) Obviousness Rejection Based on the Ichikawa, Evans, Sundberg and Fey References

Claims 27-28, 57-58 and 87-88 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference in view of the Evans reference and in further view of the Sundberg reference and the Fey reference (U.S. Pub. 2002/0038227). As the Ichickawa, Evans, Sundberg and Fey references fail to teach or suggest all the limitations of the rejected claims, Applicant respectfully traverses this rejection, as hereinafter set forth.

Claims 27-28 depend either directly or indirectly from independent claim 25. Independent claim 25 is directed to a method in a computer system for processing hereditary data related to the use of clinical agents by a person, comprising the steps of receiving a genetic test result value for the person, determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents and outputting an interpretation of the genetic test result value and the list of risk-associated agents. As discussed above, the Ichickawa, Evans and Sundberg references fail to teach or suggest a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 25.

The Fey reference also fails to teach or suggest a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim

25. Rather, the Fey reference discloses a method for centralized health data management. The Fey reference relates to a centralized health screening and management system. Data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. The Fey reference in no way suggests instructions computerized method steps for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test results values and a list of risk-associated agents as recited by independent claim 85. The Fey reference merely discusses storing health data in a manner that is accessible. The Fey reference does not suggest computerized steps for accessing a list of risk-associated agents for a genetic test result value that is a polymorphism value associated with an atypical event nor does it suggest outputting a list of risk-associated agents.

Accordingly, it is respectfully submitted that the Ichickawa, Evans, Sundberg and Fey references fail to teach or suggest all of the limitations of independent claim 25 and, thus, a *prima facie* case of obviousness cannot be established for this claim based upon the combination of the Ichickawa, Evans, Sundberg and Fey references. *See*, *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1438 (Fed. Cir. 1991). As claims 27-28 depend from independent claim 25, it is respectfully submitted that a *prima facie* case of obviousness based upon the combination of the Ichickawa, Evans and Sundberg references cannot be established for these claims for at least the same reasons as independent claim 25. *See*, *In re Fine*, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988) (a dependent claim is obvious only if the independent claim from which it depends is obvious); *see also*, MPEP § 2143.03. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 27-28 is respectfully requested.

Claims 57-58 depend either directly or indirectly from independent claim 55. Independent claim 55 is directed to a computer system for processing hereditary data related to the use of clinical agents by a person, comprising a receiving component for receiving a genetic test result value for the person, a first determining component for determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and an accessing component for accessing a list of risk-associated agents if the determining component determines that a genetic test result value is a polymorphism value associated with an atypical event and an outputting component for outputting an interpretation of the genetic test result value and the list of risk-associated agents. As discussed above, the Ichickawa, Evans and Sundberg references fail to teach or suggest a computer system for processing hereditary data related to the use of clinical agents by a person that includes an accessing component for accessing a list of risk-associated agents if a genetic tests result value is a polymorphism value associated with an atypical event and an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 55.

The Fey reference also fails to teach or suggest a computer system for processing hereditary data related to the use of clinical agents by a person that includes an accessing component for accessing a list of risk-associated agents and an outputting component for outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Rather, the Fey reference discloses a method for centralized health data management. The Fey reference relates to a centralized health screening and management system. Data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. The Fey reference in no way suggests

accessing component for accessing a list of risk-associated agents and outputting component for outputting an interpretation of one or more genetic test results values and a list of risk-associated agents as recited by independent claim 85. The Fey reference merely discusses storing health data in a manner that is accessible. The Fey reference does not suggest a computer component for accessing a list of risk-associated agents for a genetic test result value that is a polymorphism value associated with an atypical event nor does it suggest a computer component outputting a list of risk-associated agents.

Claims 89-90 depend either directly or indirectly from independent claim 85. Independent claim 85 is directed to a computer readable medium comprising instructions for processing hereditary data related to the use of clinical agents by a person, comprising the steps of receiving a genetic test result value for the person, determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents and outputting an interpretation of the genetic test result value and the list of risk-associated agents. As discussed above, the Ichickawa, Evans and Sundberg references fail to teach or suggest a computer readable medium comprising instructions for processing hereditary data related to the use of clinical agents by a person that includes accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claim 85.

The Fey reference also fails to teach or suggest instructions on a computer readable medium that includes accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 85. Rather, the Fey reference discloses a method for centralized health data management. The Fey reference relates to a centralized health screening and

management system. Data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. The Fey reference in no way suggests instructions on a computer readable medium that include accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test results values and a list of risk-associated agents as recited by independent claim 85. The Fey reference merely discusses storing health data in a manner that is accessible. There are no instructions in the Fey reference for accessing a list of risk-associated agents for a genetic test result value that is a polymorphism value associated with an atypical event nor does it suggest outputting a list of risk-associated agents.

In light of the above arguments, Applicants submit that claims 25-30, 55-60, and 85-90 are in condition for allowance. As such, Applicant respectfully request that a timely Notice of Allowance be issued in this case. It is believed that no fee is due. However, the Commissioner is hereby authorized to charge any amount required to Account No. 19-2112. A duplicate copy of this sheet is enclosed.

An action on the merits is solicited.

Respectfully submitted,

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AMENDMENTS TO THE DRAWINGS:

The attached sheet of drawings includes changes to FIG. 5. This sheet replaces the original sheet including FIG. 5. The sheet was amended to show the elements of FIG. 5 that were difficult to see due to dark shading on the Figure.

Attachments: Replacement Sheet

Annotated Sheet Showing Changes